REMARKS

In the Office Action dated December 6, 2007, the Examiner states that this application contains the following groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claims 1-18 drawn to a method of detecting the presence of anti-folate antibodies.

II. Claims 19 and 22, drawn to a method of diagnosis of a folate-sensitive abnormality.

III. Claims 20 and 23, drawn to a method of screening for a subject at risk.

IV. Claims 21 and 24, drawn to a method of prevention of a folate sensitive abnormality.

In order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group I, Claims 1-18 drawn to a method of detecting the presence of anti-folate antibodies. However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

Applicants respectfully submit that a requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression 'technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

The Examiner alleges that Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The Examiner states that the first product claimed is the kit of Claim 11. The Examiner alleges that all the elements of the kit were described previously and used for detecting antibodies to folate receptors in an ELISA assay. The Examiner refers to U.S. Patent No. 6,555,388 to Boches et al. and Hoier-Madsen et al. (*Bioscience Reports* 7: 553-57, 1987).

Applicants respectfully submit that unity of invention is the issue at hand. The Examiner should not rely on an evaluation regarding novelty and/or inventive step of the present invention over certain prior art in order to determine whether the requirement of unity of invention is satisfied under PCT Rule 13.1. Applicants should be given the opportunity to argue on the merits during prosecution whether the claims involve novelty and/or inventive step. Restriction of the claims at this stage would deny Applicants such an opportunity.

Moreover, Claim 11 is directed to a test kit for detecting autoantibodies to FRs (folate receptors) in a biological sample from a subject. In this regard, Applicants observe that U.S. Patent No. 6,555,388 is directed to a method of measuring folate or vitamin B12 in serum or plasma. See, e.g., the Abstract of U.S. Patent No. 6,555,388. In addition, Hoier-Madsen et al. disclose certain rabbit antibodies against folate binding protein (FBP) in human milk. Applicants respectfully submit that FBP includes proteins that can bind folate, such as a folate receptor protein (FR). Thus, Hoier-Madsen et al. do not disclose or suggest any antibody or any other agent that detects antoantibodies to FR.

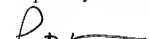
Applicants respectfully submit that the present application is predicated in part on the recognition that folate-sensitive abnormalities are caused by the presence of autoantibodies to the

FRs in a subject's body fluids, such as serum. The unique recognition of the present application provides the basis for detecting the presence of autoantibodies to folate receptors in a biological sample from a subject in order to diagnose a folate-sensitive abnormality or a disorder in the subject, to screen a woman subject at risk of the abnormality or disorder or a kit for detecting the autoantibodies to FRs. It is respectfully submitted that all claims presented in the present application share the technical feature of detecting the presence of autoantibodies to folate receptors in a biological sample from a subject. It is submitted that the present claims, when considered as a whole, define a contribution over the prior art, and should be examined in the same application. Applicants respectfully submit that Groups I-IV are different aspects of a single invention.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined four groups, one from the other, as presented by the Examiner.

Accordingly, it is respectfully submitted that Claims 1-24 satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the pending claims.

Respectfully submitted,



Peter I. Bernstein
Registration No. 43,497

SCULLY, SCOTT, MURPHY & PRESSER, P.C.
400 Garden City Plaza - Ste. 300
Garden City, New York 11530
(516) 742-4343
ZY:ab